1646

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE #9

In re Application of:

Goldberg et al.

Application No: **10/050,686**

Filed: January 16, 2002

For: *Compositions and Methods for Treatment of Muscle Wasting*

Examiner: Unassigned

Art Unit: 1646

Attorney Docket No.: HMV-070.01

CERTIFICATE OF MAILING

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, postage prepaid, in an envelope addressed to Commissioner for Patents, Washington, D.C. 20231 on: **November 11, 2002.**

Terrill Williams

Commissioner for Patents
Washington, DC 20231

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR 1.97 (b)(3)

Sir:

In compliance with the requirements of 37 C.F.R. 1.56 and 1.97(b)(3), submitted herewith on Form PTO-1449 is a list of publications known to Applicants and their Attorney/Agent. A copy of each publicly available document is also being submitted herewith.

Applicants have listed dates of publication on the attached PTO-1449 for the cited documents based on information presently available to the undersigned. However, the listed publication dates should not be construed as the dates the cited documents were actually published or otherwise publicly available.

This submission does not represent that a search has been made or that no better art exists. Nor does it constitute an admission that the cited documents are material or constitute "prior art." If the Examiner applies the listed documents as prior art against any claim in the application and Applicants determine that the cited documents do not constitute "prior art" under United States law, Applicants reserve the right to present to the Office the relevant facts and law regarding the appropriate status of such documents. Applicants further reserve the right to take

appropriate action to establish the patentability of the disclosed invention over the listed documents, should one or more of the referenced documents be applied against the claims of the present application.

Applicants respectfully request that the Examiner consider the listed documents and indicate that they were considered by making appropriate notations on the attached Form 1449.

Under 37 C.F.R. § 1.97 (b)(3), this Information Disclosure Statement is being filed before the mailing date of the first Office Action on the merits; therefore, no fee is believed to be due in connection with this submission. However, the Commissioner is authorized to charge any deficiencies or credit any overpayment to/from our **Deposit Order Account, No. 06-1448**.

Should there be any questions after reviewing this paper, the Examiner is invited to contact the undersigned at (617) 832-1177.

Respectfully Submitted,

Date: November 11, 2002

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Form PTO-1449 **INFORMATION DISCLOSURE CITATION IN AN APPLICATION** *(Use several sheets if necessary)*	Docket Number (Optional) HMV-070.01	Application Number 10/050,686
	Applicant Goldberg, et al.	
	Filing Date January 16, 2002	Group Art Unit 1646

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	6,124,123	9/26/00	Bandman, et al.			
	AB	6,001,619	12/14/99	Beach, et al.			
	AC	5,972,636	10/26/99	Goldberg			
	AD	6,087,122	07/11/00	Hustad, et al.			
	AE	5,726,025	03/10/98	Kirschner, et al.			
	AF	5,693,617	12/2/97	Stein, et al.			

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	Translation YES	Translation NO
	BA							

OTHER DOCUMENTS

(Including Author, Title, Date, Pertinent Pages Etc.)

	CA	Attaix, D., et al., "Regulation of ATP-Ubiquitin-Dependent Proteolysis in Muscle Wasting," *Reprod. Nutr. Dev.* 34: 583-597, (1994)
	CB	Bartel et al., "The Recognition Component of the N-end Rule Pathway", *The EMBO Journal, Vol.* 9:3179-3189, (1990)
	CC	Bodine, Sue C., et al., "Identification of Ubiquitin Ligases Required for Skeletal Muscle Atrophy" , *Science Magazine,* November 2001, Vol. 294
	CD	Cenciarelli, C., et al., "Identification of a Family of Human F-Box Proteins", *Current Biology,* 9: 1177-1179 Supplementary material, October 11, 1999
	CE	Cenciarelli, C., et al., "Identification of a Family of Human F-Box Proteins, *Current Biology,* Vol. 9, No. 20, 1177-1179, October, 1999
	CF	Chiaur, D. S., et al., "Five Human Genes Encoding F-Box Proteins: Chromosome Mapping and Analysis in Human Tumors" , *Cytogenetics and Cell Genetics,* 88: 255-258 (2000)
	CG	Craig, Karen L., et al. "The F-Box: A New Motif for Ubiquitin Dependent Proteolysis in Cell Cycle Regulation and Signal Transduction", *Progress in Biophysics & Molecular Biology,* 72:299-328, (1999)
	CH	Goldberg, Alfred L., et al., "The Cellular Chamber of Doom: Structures called Proteasomes Inside Cells Continuously Destroy Proteins. Several Common Diseases Result When the Process Works Too Zealously - Or Not At All", *Scientific American, Inc.*, 68- 73, January, 2001.
	CI	Goldberg, Alfred L., "Probing the Proteasome Pathway", *Nat Biotechnol.* , 18(5):494-6., May 2000

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	CJ	Goldberg, et al. , "New Insights Into The Mechanisms and Importance of the Proteasome in Intracellular Protein Degradation" *Biol Chem..*, Vo. 378(3-4):131-40, March/April 1997
	CK	Goldberg, Alfred L., et al., "Functions of the Proteasome: the Lysis at the End of the Tunnel" *Science.* Apr 28;268(5210):522-3, 1995.
	CL	Gomes, Marcelo D., et al. "Atrogin-1, A Muscle-Specific F-Box Protein Highly Expressed During Muscle Atrophy", *PNAS,* Vol. 98, No. 25, 14440-14445, December 4, 2001.
	CM	Hershko, Avram, et al., "The Protein Substrate Binding Site of the Ubiquitin-Protein Ligase System", *The Journal of Biological Chemistry,* Vol. 261, No. 26, pp 11192-11999, September 15, 1986
	CN	Jagoe, et al, "What Do We Really Know About the Ubiquitin-Proteasome Pathway in Muscle Atrophy?" , *Curr Opin Clin Nutr Metab Care,* 4(3):183-90, May 2001
	CO	Kisselev, et al., "Proteasome Inhibitors: From Research Tools to Drug Candidates" *Chem Biol.* (8):739-58, Aug. 8, 2001
	CP	Lecker, Stewart H., et al. , "Muscle Protein Breakdown and the Critical Role of the Ubiquitin-proteasome Pathway in Normal and Disease States" *J Nutr.* 129(1S Suppl):227S-237S, January, 1999
	CQ	Lee, at al., "Proteasome Inhibitors:Valuable New Tools for Cell Biologists Trends" *Cell Biol.* (10):397-403. *trends in Cell Biology(Review),* Vol. 8, October 8, 1998
	CR	Llovera M. et al. , "Muscle Wasting Associated with Cancer Cachexia is Linked to an Important Activation of the ATP-Dependent Ubiquitin-mediated Proteolysis" , *Int. J. Cancer* 61: 138-141, 1995
	CS	Lyapina, Svetlana A., et al. "Human CUL1 Forms an Evolutionarily Conserved Ubiquitin Ligase Complex (SCF) with SKP1 and an F-Box Protein, *Proc. Natl. Acad. Sci, USA,* Vol. 95, pp. 7451-7456, Cell Biology, June, 1998
	CT	Mitch et al., "Mechanisms of Muscle Wasting. The Role of the Ubiquitin-proteasome Pathway", *New England Journal of Medicine,* 335(25):1897-905, December 19, 1996.
	CU	Patton, E. Elizabeth, et al., "Combinatorial Control in Ubiquitin-dependent Proteolysis: don't Skp the F-box Hypothesis", *Trends Genet.* 14: 236-243 (1998)
	CV	Skowyra, Dorota, et al., "F-Box Proteins Are Receptors that Recruit Phosphorylated Substrates to the SCF Ubiquitin-Ligase Complex", *Cell,* Vol. 91, 209-219 October 17, 1997
	CW	Solomon, et al., "Rates of Ubiquitin Conjugation Increase When Muscles Atrophy, Largely Through Activation of the N-end Rule Pathway", *Proc Natl Acad Sci U S A,* 95(21):12602-7, October 13, 1998
	CX	Tawa, et al., "Inhibitors of the Proteasome Reduce the Accelerated Proteolysis in Atrophying Rat Skeletal Muscles" *J Clin Invest.* , 100(1):197-203, July 1, 1997.
	CY	Voisin L. et al., "Muscle Wasting in a Rat Model of Long-lasting Sepsis Results from the Activation of Lysosomal, Ca^{2+}-activated, and Ubiquitin-Proteasome Proteolytic Pathways", *J. Clin. Invest.* Vol. 97, No. 7: 1610-1617, April, 1996
	CZ	Winston, Jeffrey T., et al., "A Family of Mammalian F-Box Proteins", *Current Biology,* 9: 1180-1182, October 11, 1999

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	DA	Bodine, S. C., et al., GENBANK Accession No. AY059629, December 13, 2001
	DB	Bodine, S. C., et al., GENBANK Accession No. AY059628, December 13, 2001
	DC	Stitt, T.N., et al., "Novel Ubiquitin Ligase Genes Expressed During Skeletal Muscle Atrophy," Abstracts of Papers Presented at the 2001 Meeting on "Proteolysis & Biological Control" Cold Spring Harbor Laboratory. May 2-6, 2001.

EXAMINER		DATE CONSIDERED

EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.